May 14, 2026

Hunan Accurate Bio-Medical Technology Co., Ltd.
% Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C
No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
CHINA

Re: K252601
Trade/Device Name: Pelvic Muscle Trainer (PC22A); Pelvic Muscle Trainer (PC22A-L); Pelvic Muscle Trainer (PC22E); Pelvic Muscle Trainer (PC22E-L)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HIR
Dated: April 14, 2026
Received: April 14, 2026

Dear Jie Yang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: The Center for Devices and Radiological Health (CDRH) does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, the Food and Drug Administraton (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSICA K. NGUYEN -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252601

Please provide the device trade name(s).

Pelvic Muscle Trainer (PC22A);
Pelvic Muscle Trainer (PC22A-L);
Pelvic Muscle Trainer (PC22E);
Pelvic Muscle Trainer (PC22E-L)

Please provide your Indications for Use below.

The device is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: May 14, 2026

1. Submitter Information

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2. Device Information

Trade/Device Name	Pelvic Muscle Trainer (PC22A); Pelvic Muscle Trainer (PC22A-L); Pelvic Muscle Trainer (PC22E); Pelvic Muscle Trainer (PC22E-L)
Model	PC22A, PC22A-L, PC22E, PC22E-L
Common Name	Nonimplanted electrical continence device
Regulatory Class	Class II
Classification number	21 CFR 876.5320
Classification name	Nonimplanted electrical continence device
Product Code	KPI
Secondary Product Code	HIR

3. Predicate Device Identification

No.	Device name and model	K number	Manufacturer
Primary Predicate	Yarlap II	K160773	International Trade Group, Inc.
Secondary Predicate	ApexMV	K182022	InControl Medical, LLC

The predicate devices have not been subject to a design-related recall.

4. Device Description

The Pelvic Muscle Trainer is an over-the-counter, non-implantable, home use device intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment

of stress, urge, and mixed urine incontinence which help users to achieve pelvic floor muscle strengthening for maintaining urinary continence in adult women.

The Pelvic Muscle Trainer consists of a handheld control unit with reusable (single-patient use) vaginal electrode and/or vaginal probe. The main unit is made out of ABS plastic. The vaginal probe is inserted vaginally and inflated by the end user to ensure a customized fit for the biofeedback feature of the device. The inflation system consists of an internal air pump embedded within the main unit, connected to the inflatable vaginal probe via flexible tubing. Inflation is driven by embedded software but remains under the direct manual control of the user. The vaginal probe is made out of made out of silicone and ABS plastic.

Electrical stimulation is delivered via vaginal electrode to induce a contraction of the pelvic floor muscles. The vaginal electrode is made out of stainless steel and polypropylene. The device has 5 electrical stimulation modes: 1) P1 and P2 for mixed urinary incontinence, 2) P3 for urge urinary incontinence, and 3) P4 and P5 for stress urinary incontinence. The level of electrical stimulation is controlled by the end user using manual, push-button controls. The training results can be transmitted by Bluetooth to non-medical APP. The app incorporates an interactive game, where relaxing and contracting pelvic floor muscles result in downward and upward movements in the game, respectively.

There are a total of four models of the device: PC22A, PC22A-L, PC22E, and PC22E-L. PC22A and PC22E include both electrical stimulation and biofeedback features. However, PC22A-L and PC22E-L only provide electrical stimulation. Additionally, there are differences in appearance and orientation of buttons between models PC22A and PC22A-L, and PC22E and PC22E-L.

5. Indications for use

The device is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

6. Comparison of Technological Characteristics

The Yarlap II device is the primary predicate and used as a predicate for the electrical stimulation function and the ApexMV device is used as a predicate for the biofeedback system.

Table 1 comparison with the primary predicate

ITEM	**Subject Device K252601**	**Primary Predicate K160773**	**Comparison Result**

Trade/Device Name	Pelvic Muscle Trainer	Yarlap II	/
Indications for Use/Intended use	The device is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	Same for electrical stimulation indication. Refer to table 2 for secondary predicate for visual biofeedback(via manometry) indication.
Environments of Use	Home environment	Home environment	Same
Prescription or Over-the-Counter (OTC)	OTC	Prescription Use & OTC	Similar
Power source	3.7V DC/1600mAh rechargeable lithium battery	4 X 1.5 Volt Alkaline Batteries (standard 900mAh)	Substantially equivalent
Waveform	Biphasic, Symmetrical	Biphasic, Symmetrical	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)	40@500Ω 50 @2kΩ 95@10kΩ	40@500Ω 50 @2kΩ 95@10kΩ	Same
Maximum Output Current (mA)	80mA@ 500Ω 50mA@2kΩ 19mA@10kΩ	80mA @ 500Ω 50mA @ 2kΩ 19mA @10kΩ	Same
Pulse Width (μsec)	200~250μs	200~250μs	Same
Frequency (Hz)	12 Hz - 35Hz, program dependent	10 Hz - 35Hz, program dependent	Same for each program, See program comparison table 3 below
For multiphasic waveforms only:	Yes	Yes	Same

-Symmetrical phases			
For multiphasic waveforms only: - Phase Duration (μsec)	100~125	100~125	Same
Net charge	0μC @ 500Ω;	0μC @ 500Ω	Same
Maximum Phase Charge	20μC	20μC	Same
Electrode Area	6.4cm^2	6.4cm^2	Same
Maximum (peak) Current Density (mA/cm2)	12.5	12.5	Same
Maximum Average Power Density (@500Ω) (mW/cm2)	3.5	3.5	Same
Adjustable range of treatment intensity	0-80mA	0-80mA	Same
Electrode dimension	93*26.6mm	92*26.6mm	Same
target population	Women with stress, urge, or mixed urinary incontinence	Women with stress, urge, or mixed urinary incontinence	Same
anatomical site	Vaginal mucosa	Vaginal mucosa	Same
Current control	0-80mA,Increase or decrease 1mA each time	0-80mA,Increase or decrease 1mA each time	Same
Voltage control	Adjust current	Adjust current	Same

Table 2 comparison with secondary predicate

ITEM	**Subject Device K252601**	**Secondary Predicate K182022**	**Comparison Result**
Trade/Device Name	Pelvic Muscle Trainer	ApexMV	/
Indications for Use	The device is intended to provide electrical stimulation and/or	ApexMV is a non-implantable muscle stimulator intended to	Same

	visual biofeedback (via manometry) for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women.	
Environments of Use	Home environment	Home environment	Same
Prescription or Over-the-Counter (OTC)	OTC	OTC	Same
Power source	3.7V DC/1600mAh rechargeable lithium battery	4 -AA Alkaline battery	Substantially equivalent
Primary function	Delivery of electrical stimulation Visual biofeedback	Delivery of electrical stimulation Visual biofeedback	Same
Biofeedback	Manometric Air pressure, 0-100 mmHg(0-2psi)	Manometric Air pressure, .01 – 2 psi	Same
Inflation Mechanism	Air pump	Manual air pump	Substantially equivalent
Inflation Control	User-regulated: Manually controlled by the end user via buttons to a customized fit.	User-regulated: Manually inflated by the end user to a customized fit.	Substantially equivalent
Maximum Inflation Capacity	90 x 34 x 43 mm	99.06 x 35.56 x 43.18 mm	Substantially Equivalent
Biofeedback Monitoring	Pressure-based, continuous visual display.	Pressure-based, continuous visual display.	Same
target population	Women with stress, urge, or mixed urinary incontinence	Women with stress, urge, or mixed urinary incontinence	Same
anatomical site	Vaginal mucosa	Vaginal mucosa	Same
Treatment duration	10 minutes Kegel exercise(recommended)	total session time of approximately 11 minutes *7 minutes of electrical stimulation *3.5 minutes of self-directed contractions (recommended)	Substantially Equivalent

Table 3 Comparison with each program

Program Description			Rate Hz	Pulse μS	Work Sec.	Rest Sec.	Time Min.	Max. mW/cm2 80 mA	Ave. mW/cm2 30 mA	Ave. mW/cm2 45 mA	Duty cycle
Utility	Primary Predicate	Applicant									
Mixed	Program1		12	200	5	5	15	1.2	0.17	0.38	0.2%
		Program1	12	200	5	5	15	1.2	0.17	0.38	0.2%
Mixed	Program2		20	250	8	8	20	2.5	0.35	0.79	0.5%
		Program2	20	250	8	8	20	2.5	0.35	0.79	0.5%
Urge	Program3		12	200	5	10	15	1.2	0.17	0.38	0.2%
		Program3	12	200	5	10	15	1.2	0.17	0.38	0.2%
Stress	Program5		12	250	5	15	15	1.5	0.21	0.47	0.3%
		Program4	12	250	5	15	15	1.5	0.21	0.47	0.3%
Stress	Program6		35	200	6	18	20	3.5	0.5	1.11	0.7%
		Program5	35	200	6	18	20	3.5	0.5	1.11	0.7%

7. Summary of Non-Clinical Performance Testing

The following non-clinical performance data were provided in support of the substantial equivalence determination.

- Biocompatibility evaluation in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
- Electrical Safety testing according to ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- Electromagnetic Compatibility testing according to IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10 Edition 2.2 2023-01 CONSOLIDATED VERSION Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and

essential performance of nerve and muscle stimulators

- Battery safety testing according to IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
- Software Verification and Validation Testing according to FDA's Guidance " Content of Premarket Submissions for Device Software Functions"
- Cybersecurity evaluation according to FDA's Guidance "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions"
- Electrical performance testing to verify the stimulation parameters
- Use life testing to support the service life of the main unit and the vaginal electrode/probe

All pre-determined acceptance criteria were met.

8. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate devices.
With respect to the electrical stimulation function, the subject device is as safe and effective as the Yarlap II device. With respect to the biofeedback function, the subject device is as safe and effective as the ApexMV device.